

CERTIFICATE OF ANALYSIS

Product: **Biocan DHPPi**

Batch No.: **90 61 26 A**

Expiry: **28.11.2021**

Date of production: **29.11.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Lyophilised vaccine is spongy matter, white to cream or pinkish colour. After dissolving in diluent the vaccine is pink-red or yellowish colour with light opalescence.		conforms
pH	6.5 – 8.0		7.5
Sterility	Vaccine must be sterile.		sterile
Mycoplasma	Vaccine should not contain mycoplasma.		conforms
Extraneous viruses	Vaccine should not contain any extraneous viruses.		conforms
Residual humidity	Max. 3%.		2.0 %
Virus titre:			
CDV - Virus febris contagiosae canis	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀		$10^{4.1}$ TCID ₅₀
CAV-2 - Virus laryngotracheitidis contagiosae canis	min. $10^{3.5}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀		$10^{3.8}$ TCID ₅₀
CPV – Parvovirus enteritidis canis	min. $10^{4.5}$ TCID ₅₀ , max. $10^{5.5}$ TCID ₅₀		$10^{5.3}$ TCID ₅₀
CPiV-2 - Virus parainfluenzae canis	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.2}$ TCID ₅₀		$10^{3.8}$ TCID ₅₀
Virus identity	CDV: Neutralisation index ≥ 2 .		4.1
	CAV-2: Neutralisation index ≥ 2 .		3.8
	CPV: Neutralisation index ≥ 2 .		3.2
	CPiV-2: Neutralisation index ≥ 2 .		3.8

I certify that this product has been tested in the laboratories of Bioveta a.s. and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 141.



Hana Nezvalová
.....29/04/2020
Mgr. Hana Nezvalová
HEAD of QC, QP